

**REMARKS**

**New Matter**

The amendment of the specification, filed June 11, 2007, was objected to under 35 U.S.C. §132(a) because it allegedly introduced new matter into the disclosure. In response, Applicants have amended the specification to remove specific dosage and route of administration data added to several of the Examples. Applicants submit the Previously Presented portions of the specification do not contain new matter and respectfully request withdrawal of the rejection.

Applicants note that the data in question was added as suggested by the Examiner's during the interview held June 5, 2007. Applicants respectfully submit that the first paragraph of the Remarks in the Amendment of June 11, 2007, states, "The amendments in the specification have been suggested by the Examiner during the interview and do not introduce new matter as the changes simply provide further clarifications in the examples that were reduced to practice by the inventors." Applicants note that composition, dosage, route of administration and frequency data are scattered throughout the specification, which even the Examiner recognized during the interview of June 5, 2007, as discussed in more detail below. Thus, the application as a whole discloses the various parameters even if all of the individual examples do not.

**Claim Rejection - 35 U.S.C. § 112**

The rejection of claims 22-47, and newly added claim 48, under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement, was maintained for reasons of record. Specifically, the claims were rejected because the specification allegedly does not provide sufficient explanation for those of skilled in the art to make and/or use the claimed invention. The allegedly lacking information includes the actual composition administered, the dosage, the route of administration and the frequency. This rejection is respectfully traversed.

"An inventor need not, however, explain every detail since he is speaking to those skilled in the art." DeGeorge v. Bernier 768 F.2d 1318, 1323 (C.A.Fed., 1985)(citing In re Howarth, 654

F.2d 103, 105 (CCPA 1981). A disclosure is sufficient even if it would require that one skilled in the art conduct some experimentation. White Consolidated Industries, Inc. v. Vega Servo-Control, Inc., 713 F.2d 788, 791 (Fed. Cir. 1983). "The amount of required experimentation, however, must be reasonable." Id. See also, In re Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991) ("That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'"). Further, failure to disclose a dosage level does not constitute per se lack of enablement. Cross v. Iizuka, 753 F.2d 1040, 1051 (Fed. Cir 1985)(holding that the determination of the dosage level was within the skill in the art for derivative compounds when dosage levels for the parent compound was known). Compare In re Gardner, 427 F.2d 786, 788-89 (C.C.P.A. 1970)(finding a lack of enablement given the disclosure of specific dosage units ranging all the way from 10 mg. to 150 mg., "coupled with the total absence of any reference to a host, which, in turn, is coupled with an insistence that, within the claimed invention, the host is not necessarily a human being") (emphasis added). Finally, Applicants note that that the specification need not describe the exact parameters of each combination that falls within the range claims the patent. Union Oil Co. of California, v. Atlantic Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000)(finding adequate written description while noting that "the Patent Act and this court's case law require only sufficient description to show one of skill art that the inventor possessed the claimed invention at the time of filing").

In the present case, Applicants submit that the specification provides clear and sufficient guidance to one of ordinary skill in the art on how to make and/or use the claimed invention. Specifically, in contrast to Gardner, the present application includes numerous references to human hosts. (See e.g., Examples 4-8). Indeed, all of the examples are illustrated with human patients. Further, regarding the dosage and composition, Example 1 provides 10 different recipes for 0.1 ml therapeutic doses. Example 6 teaches giving patients 0.1 ml doses at a rate of 1 per week. Additionally, Example 2 teaches the preparation of a pharmaceutical composition in great detail. Regarding frequency and duration, example 4 teaches treating the patient once a week for four weeks while example 7 teaches treating patients according to a conventional regimen for three months. Regarding the route of administration, the specification teaches that asthma medications

may be inhaled or taken orally with the preferred method being inhalation. (See pages 2-3 of the instant application). *One of ordinary skill in the art reading the specification would clearly understand that typical treatment conditions would comprise giving a patient approximately 0.1 ml doses once a week for four weeks to three months.*

In addition, Dr. Khamar, one of the inventors on this application, submits herewith a declaration under 37 C.F.R. § 1.132 providing additional experimental data supporting the compositions, dosages, and treatment regimens taught in the specification. The additional experimental data in the Rule 132 declaration of Dr. Khamar simply provide further clarifications of the examples that were reduced to practice by the inventors. However, as explained in paragraph 9 of the Rule 132 of Dr. Michael Ross, MD, the additional data in the Rule 132 declaration of Dr. Khamar are nothing more than "minor details." However, "the omission of minor details does not cause a specification to fail to meet the enablement requirement" as the "minor details" supplement, *not* substitute the specification. See Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361 (Fed. Cir. 1997). In short, Applicants submit that one of ordinary skill in the art reading the specification would have sufficient guidance to prepare a pharmaceutically effective composition, dosage and treatment regimen as claimed and respectfully request withdrawal of the rejection.

In view of the above amendment, applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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